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EDITORIAL COMMENT

Coronary Multidetector Computed Tomography

A New Standard for Preoperative Risk Assessment?*

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For investigators interested in cardiovascular disease, these are exciting times. It is rare that a new technology with the potential to revolutionize the understanding and management of a major disease process is introduced. For coronary artery disease (CAD), it might be that time, because multidetector computed tomography (MDCT) is a fast, noninvasive, and robust method for visualization of the entire coronary artery tree in a single breath-hold. The research activity over the last five years, bearing numerous publications suggesting the feasibility of coronary MDCT to detect and characterize coronary artery stenosis, lays the foundation for an unprecedented opportunity to: 1) enhance our understanding of the natural history of CAD, and 2) explore the potential of coronary MDCT to improve patient management by means of cost and/or risk reduction.

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The study by Gilard et al. (1) in this issue of the *Journal* is one of the first studies to address the latter. The primary end point of this blinded, observational cohort study was to determine the number of invasive angiograms that could be avoided before aortic valve replacement (AVR) by implementation of a preoperative coronary MDCT. The results certainly demonstrate the potential of coronary MDCT to reliably exclude the presence of coronary stenosis (sensitivity and negative predictive value 100%) in this patient cohort given an Agatston score <1,000. Although intriguing, this research represents an initial assessment of a new technology in a specific subset of patients. Thus, it might be helpful to consider the process of drug approval as an analogy in order to determine the level of scientific evidence that is necessary before performing coronary MDCT routinely as part of the preoperative management of patients with severe aortic stenosis.

Feasibility studies demonstrating the accuracy and reproducibility of a new technology are a necessary first step in assessing its clinical utility. In addition, there should be a compelling rationale for its implementation in the clinical arena. This situation is typically found when the current strategy for a specific clinical condition is imperfect, leaving enough room for improvement in either patient safety or cost-effectiveness. If both of these conditions are met, observational studies can determine whether the selected patient population and the clinical end points are appropriate. These studies often also permit a preliminary assessment of safety, cost, and cost effectiveness—information that is crucial to justify costly randomized diagnostic trials as the final step of the process. Only validation at this level will eventually enable the practice of evidenced-based medicine, permit recommendations by professional societies, and unequivocally justify reimbursement by third party payers.

If we apply these principles to the technology and clinical application at hand, there are more than 35 studies that have demonstrated the high sensitivity and specificity of both 16- and 64-slice MDCT for the detection of coronary stenosis (2). The fact that all studies thus far have been performed at single centers in a very specific patient subsets remains a limitation, and a multicenter trial, which has yet to be performed, is warranted.

Current patient management requires invasive coronary angiography primarily to exclude the presence of significant coronary artery stenosis. Echocardiography is the method of choice to diagnose the severity of aortic stenosis and provides accurate information regarding valve morphology, LV function, and hemodynamic significance. Thus, the opportunity to non-invasively exclude significant CAD provides a compelling rationale for using coronary MDCT before AVR. Hence, the stage is set for the current study.

Three pieces of information are crucial to assess the potential of coronary MDCT to improve safety and cost-effectiveness of the current preoperative workup in patients scheduled for AVR:

1. Prevalence of significant CAD in this population (i.e., how many angiograms can be avoided if the new technique is perfect); this determines the maximum benefit that can be achieved
2. Accuracy of coronary MDCT to detect significant CAD in exams with optimal image quality
3. Fraction of non-diagnostic coronary MDCTs due to impaired assessability of coronary segments with severe calcification or motion artifacts.

The current study was performed in a French patient population that had a low prevalence of CAD (20%). The sensitivity and negative predictive value were 100%, the specificity was 80%, and the positive predictive value was 55% for coronary MDCT to identify a significant coronary stenosis in patients with diagnostic examinations. Coronary MDCT was non-diagnostic in patients with an Agatston

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score >1,000 (approximately 20%), rendering the following hypothetical scenario for 100 patients with severe aortic stenosis scheduled for AVR.

First, according to this algorithm, all 100 patients would undergo screening for coronary artery calcification. Twenty patients would have an Agatston score of 1,000 and would go on to invasive coronary angiography. The remaining 80 patients would undergo contrast enhanced MDCT. All patients with significant CAD (n = 16) would be correctly identified, but a significant coronary stenosis would be erroneously diagnosed in 17 patients (specificity 80%). Subsequently, patients with an Agatston score >1,000 (n = 20), true positive CAD patients (n = 16), and false positives (n = 17) would undergo cardiac catheterization. Comparison of traditional standard of care (assuming all patients undergo invasive angiography) versus coronary MDCT-guided decision-making yields a total savings of 47 invasive angiograms in the MDCT arm.

Although this analysis reflects the French population, the situation in the U.S. is different, where patients undergoing AVR are older, severe coronary calcification is found more frequently (approximately 25%), and the prevalence of CAD is higher (approximately 60%) (3). In this population, approximately 25 patients would be expected to have an Agatston score >1,000 and only 75 patients would undergo contrast-enhanced MDCT. All patients with significant CAD (n = 45) would be correctly identified, but a significant coronary stenosis would be erroneously diagnosed in 12 patients (specificity 80%). Subsequently, the patients with an Agatston score >1,000 (n = 25), true positive CAD patients (n = 45), and false positives (n = 12) would undergo cardiac catheterization. Thus, coronary MDCT would yield a total savings of only 18 invasive angiograms in the MDCT arm.

Although the data provided by Gilard et al. (1) clearly support the notion that coronary MDCT might be beneficial for the preoperative management of patients with aortic stenosis, the two aforementioned scenarios demonstrate the significance of the prevalence of CAD and thus the patient population as to whether coronary MDCT might improve the safety and cost-effectiveness of the current standard of care. It also becomes evident that severe coronary calcification is currently a limiting factor, and thus the elimination of calcium blooming artifacts is of utmost importance for the success of coronary MDCT. Whereas the authors performed a receiver-operator characteristic analysis on their own data, which suggested a threshold of an Agatston score >1,000 to be linked to non-diagnostic examinations, this observation is limited, because no prospective evaluation has been performed. In fact, a single large calcified plaque in a proximal location might prevent exclusion of a significant coronary stenosis. It is conceivable that, until the calcium problem has been solved, only a select group of patients undergoing AVR in the U.S. (i.e., younger patients, patients with bicuspid valves) might benefit from coronary MDCT.

Preoperative management is only one of many potential applications of coronary MDCT but exemplifies the larger challenge ahead of us: to improve physicians' ability to make informed decisions and conduct evidence-based medicine with coronary MDCT.

There is now a window of opportunity to provide these data and to potentially demonstrate that coronary MDCT improves patient management in terms of diagnostic accuracy, clinical decision-making, and cost effectiveness. Because this window might be narrow, these ambitious goals may only be achieved in a major collaborative effort between cardiologists, radiologists, and public health researchers.

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